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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,731	02/04/2002	Jeffrey Morse Holloway	71086	8128

22242 7590 10/14/2003

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 10/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,731	Applicant(s) HOLLOWAY ET AL.	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-5, 7, 14, 16, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz et al (U.S.P.N. 5,981,163) in view of Platz et al (U.S.P.N. 6,187,572).

With respect to claims 1, 5, 14, and 19, Horowitz et al teaches the following: a method of irradiating microbes in a platelet composition (col.6, lines 27-33), illuminating the fluid with pulses of light (col.6, lines 60-62), the fluence greater that about 0.001 j/cm^2 (col.6, lines 57-59), and at least about 2 logs (col.10, lines 9-11). Horowitz et al teaches that the platelet aggregation improved from about 70% to more that 90% of control levels, meaning that the decrease of platelet aggregation is not more that about 40%. However, Horowitz et al fails to disclose a range for the wavelength and repeating the illumination of the platelet composition every 6 hours. Platz et al discloses a range for the wavelength (col.28, line 67) and repeating the illumination every 2 minutes for a total time of 10 minutes (col.28, lines 65-67 and col.29, lines 1-3) and also illuminating continuously for 6 hours (col.35, lines 37-38). In addition, Platz et al teaches illuminating for 90 minutes to achieve a certain log viral reduction (col.35, lines 57-58). Thus. It would have been obvious to one having ordinary skill in the art to modify Horowitz et al method to include a step of repeating illumination every certain number of hours in order to achieve a desired value for the log reduction of viruses (col.35, lines 57-58).

With respect to claims 3-4, 7, 16, and 21, Horowitz et al teaches that any type of platelet concentrate can be illuminated (col.6, lines 29-30), and a fluence of 0.2 m/cm^2 (col.6, lines 58-59)

5. Claims 2, 6, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz et al (U.S.P.N. 5,981,163) in view of Platz et al (U.S.P.N. 6,187,572) and further in view of O'Dwyer et al (U.S.P.N. 6,312,931).

With respect to claims 2, 6, 15, and 20, both Horowitz et al and Platz et al fail to disclose a specific spectral range and a pulse duration. However, O'Dwyer et al teaches a spectral range (col.4, line 46) and a pulse duration (col.4, lines 44-45). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Horowitz et al to include short durations of time in order to protect biomolecules of interest while inactivating pathogens (O'Dwyer et al, col.4, lines 37-40)

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz et al (U.S.P.N. 5,981,163) in view of Platz et al (U.S.P.N. 6,187,572) and further in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claim 8, Horowitz et al teaches the following: a method of irradiating microbes in a platelet composition (col.6, lines 27-33), illuminating the fluid with pulses of light (col.6, lines 60-62), and at least about 2 logs (col.10, lines 9-11). Horowitz et al teaches that the platelet aggregation improved from about 70% to more that 90% of control levels, meaning that the decrease of platelet aggregation is not more that about 40%. However, Horowitz et al fails to disclose a range for the wavelength and flowing the platelet composition. Platz et al discloses illuminating at 320 nm (col.28, line 67) but fails to teach flowing the platelet composition. Goodrich, Jr. et al teaches flowing blood compositions (col.20, example 4) in an apparatus such that the treatment chamber must be at least 1% transmissive to light in order to inactivate blood

components (figure 7, 164). Thus, it would have been obvious to one having ordinary skill in the art to substitute the batch method of Horowitz et al with the continuous method of Goodrich, Jr. et al as taught by Goodrich, Jr. et al (col.9, lines 17-18 and line 51).

7. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz et al (U.S.P.N. 5,981,163) in view of Platz et al (U.S.P.N. 6,187,572) and further in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337) and O'Dwyer et al (U.S.P.N. 6,312,931).

With respect to claims 9 11, and 13, Horowitz et al discloses illuminating (col.6, lines 54-55) with a fluence at 254nm (col.21, line 57) such that most of the fluence is concentrated within a range of 200 to 300 nm and teaches that any type of platelet concentrate can be illuminated (col.6, lines 29-30). However, with respect to claims 10 and 12, Horowitz et al fails a pulse duration range and flowing the platelet composition. With respect to claim 12, Goodrich, Jr. et al teaches flowing blood components past UV lights (figure 7, 164), but fails to teach a pulse duration range as disclosed in claim 10. With respect to claim 10, O'Dwyer et al teaches a pulse duration range (col.4, lines 44-46). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Horowitz et al to include short durations of time in order to protect biomolecules of interest while inactivating pathogens (O'Dwyer et al, col.4, lines 37-40).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Dwyer et al (U.S.P.N. 6,312,931).

10. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claim 17, O'Dwyer et al discloses a method of inactivating nucleic acid strand, which is within a cellular membrane (endogenous, col.4, lines 4-5) using incoherent polychromatic light in a broad spectrum (abstract, lines 8-12).

With respect to claim 18, O'Dwyer et al discloses inactivating nucleic acid, which is contained as part of a mammalian cell (col.4, lines 5-6).

Conclusion

11. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Cimino et al (U.S.P.N. 5,565,320) and Hei (U.S.P.N. 6,544,727) teache similar methods for decontaminating platelets.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
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AU 1744

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